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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,606	07/24/2006	Katsutoshi Yoshizato	2006_0865A	5460

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EXAMINER	
MACAULEY, SHERIDAN R	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
04/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,606	YOSHIZATO ET AL.	
	Examiner	Art Unit	
	Sheridan R. MacAuley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *2,3 and 9-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/5/2006, 8/31/2006, 9/8/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending.

Election/Restrictions

1. Applicant's election of Group I (claims 1 and 4-8) in the reply filed on February 25, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement for restriction is still deemed proper and is therefore made FINAL.

2. Claims 2, 3 and 9-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. Claims 1 and 4-8 are examined on the merits in this office action.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Reynolds et al. (Development, 1996, 122:3085-3094; document cited in IDS). Claim 1 recites a hair growth method, which comprises transplanting a composition containing

the following components to an incised epidermal site: (a) dermal papillae or dermal papilla cells; and (b) epidermal tissue or epidermal cells. Claim 8 recites the hair growth method according to claim 1, wherein the dermal papilla cells of the component (a) are cultured cells.

6. Reynolds teaches a hair growth method wherein a composition containing dermal papilla cells and epidermal cells is transplanted into an incised epidermal site (p. 3088, par. 3-5, p. 3089, par. 2-4). Reynolds teaches that the dermal papilla cells are cultured cells (p. 3088, par. 2).

7. Therefore, Reynolds anticipates all of the limitations of the cited claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolowacz et al. (US 2003/0161815 A1) in view of Reynolds et al. (Development, 1996, 122:3085-3094; document cited in IDS). Claim 1 recites a hair growth method, which comprises transplanting a composition containing the following components to an incised epidermal site: (a) dermal papillae or dermal papilla cells; and (b) epidermal tissue or epidermal cells. Claim 4 recites the hair growth method according to claim 1, wherein the incised epidermal site is formed by incision of a part of dermis and whole epidermal layer. Claims 5 and 6 recite the hair growth method according to claim 1, wherein the components are derived from human, specifically human scalp. Claim 7 recites the hair growth method according to claim 6, wherein the incised epidermal site is formed in human scalp. Claim 8 recites the hair growth method according to claim 1, wherein the dermal papilla cells of the component (a) are cultured cells.

12. Wolowacz teaches a hair growth method wherein a composition containing dermal papilla cells is transplanted to an incised epidermal site (abstract, p. 1, par. 13).

Wolowacz teaches that the cells are delivered to the dermis (abstract); thus, the incision of Wolowacz is formed by incision of a whole epidermal layer and part of a dermal layer. Wolowacz teaches that the components are derived from human scalp, that the incised epidermal layer may be human scalp, and that the dermal papilla cells are cultured cells (p. 2, par. 19, 26). Wolowacz does not specifically teach the use of a composition containing epidermal tissue or epidermal cells in addition to the dermal papilla cells.

13. Reynolds teaches a hair growth method wherein a composition containing dermal papilla cells and epidermal cells is transplanted into an incised epidermal site (p. 3088, par. 3-5, p. 3089, par. 2-4).

14. At the time of the invention, a method comprising nearly all of the claimed elements was known, as taught by Wolowacz. Furthermore, it was known at the time of the invention that epidermal cells, along with dermal papilla cells, can be delivered to incised epidermal sites in hair growth methods that are similar to the claimed method, as taught by Reynolds. One of ordinary skill in the art would have been motivated to combine these teachings because Reynolds teaches that epidermal cells can be used to revive the inductive status of dermal papilla cells (p. 3092, col. 2, par. 3). Furthermore, Wolowacz teaches the desirability for the dermal papilla cells to be in close proximity to epidermal cells (p. 3, par. 27). One would thus have recognized the desirability to deliver epidermal cells as well as dermal papilla cells to an incised site in a hair growth method. One or ordinary skill in the art would have had a reasonable expectation of success in practicing the claimed method because Reynolds teaches the implantation of a range of tissues into incised epidermal sites (p. 3088, par. 2-4) and

Wolowacz teaches that the method allows for precise and accurate delivery of cells to the patient (p. 1, par. 13). It would therefore have been obvious to one or ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

15. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A. Davis/
Primary Examiner, Art Unit 1651